

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Comparison the efficacy of lavender aroma and valerian in reducing labor pain and Progress of labor in nulliparous women

#### Protocol summary

2015-05-30, 1394/03/09

##### Summary

The aim of this double blind randomized trial, is evaluation of the effects of Lavender aroma and Valerian in reducing labor pain and progress of labor in nulliparous women in Hazrate Fateme hospital in Miandoab. Enrolled mothers will be randomly allocated into 3 groups (Lavender, Valerian or placebo) using block randomization method. Lavender, Valerian and a placebo oils with similar glasses and appearance will be prepared by Bareej Essence Pharmacotical Company. The aromatic substance will be impregnated by the researcher assistant and the packets will be prepared. Participants will enter to the study in order number written on each envelope. Labor pain intensity will be evaluated using Visual Analogue Scale when cervix dilatation is 4 cm in 3 groups. Then researcher opens the corresponding subject envelope and places drops from Glass labeled 1, 2 or 3 on a cotton ball and the patient will smell it for 10 minutes every one hour. The amniotic fluid, duration of rupture of membranes, liquid paints, fetal heart rate, medications, cervical dilatation and fetal descent rate, number and duration of contractions, the baby's Apgar score at one and five minutes of observation and examination will be recorded. The Pain also will be measured by Visual Analog Scale in dilatations 6, 8, 9 and 10 centimeter.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201504236582N10**  
Registration date: **2015-05-30, 1394/03/09**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

##### Registrant information

###### Name

Mahin Kamalifard

###### Name of organization / entity

Tabriz University of Medical Sciences and Health Services

###### Country

Iran (Islamic Republic of)

###### Phone

+98 414796770

###### Email address

kamalifardm@gmail.com

##### Recruitment status

###### Recruitment complete

##### Funding source

Tabriz University of Medical Sciences

##### Expected recruitment start date

2015-03-21, 1394/01/01

##### Expected recruitment end date

2015-10-23, 1394/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the efficacy of lavender aroma and valerian in reducing labor pain and Progress of labor in nulliparous women

##### Public title

Comparison the efficacy of lavender aroma and valerian in reducing labor pain and Progress of labor in nulliparous women

##### Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion Criteria: Primiparous pregnancy; age 18-35; gestational age of 37-41 w; singleton fetus; active phase; cephalic presentation; no smoking; no addiction; no Lack of vision; no history of chronic heart diseases, lung diseases, according to the patient's expression; the absence of eclampsia; and placenta previa; no PROM for more than 18 hours; no history of infertility; willingness to participate in the study; no history of sensitivity; the presence of low-risk pregnancies. Exclusion Criteria: Get analgesic medication during the 3 hours before the start of the study; systolic blood pressure less than 95 mm Hg.

## Age

From **18 years** old to **35 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **141**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

##### Street address

Central Building No. 2, Research Administration, Tabriz University of Medical Sciences, Daneshgah st.

##### City

Tabriz

##### Postal code

#### Approval date

2015-03-09, 1393/12/18

#### Ethics committee reference number

93192

## Health conditions studied

### 1

#### Description of health condition studied

Labor pain

#### ICD-10 code

O83.8

#### ICD-10 code description

Other specified assisted single delivery

## Primary outcomes

### 1

#### Description

intensity of labor pain

#### Timepoint

before intervention, 6-8-10cm of cervix dilatation

#### Method of measurement

VAS (Visual Analog Scale)

## Secondary outcomes

### 1

#### Description

The duration of the active phase

#### Timepoint

each 2 hour

#### Method of measurement

vaginal examination

### 2

#### Description

Duration of the second stage of labor

#### Timepoint

from full dilatation until Time of Birth

#### Method of measurement

Questionnaire

### 3

#### Description

Neonatal outcomes (The first and fifth minute Apgar scores and Refer to the NICU)

#### Timepoint

After birth

#### Method of measurement

Questionnaire

### 4

#### Description

Type of delivery

#### Timepoint

After birth

#### Method of measurement

Questionnaire

### 5

#### Description

Side effects (Nausea and vomiting)

**Timepoint**

During the study

**Method of measurement**

checklist

**Intervention groups****1****Description**

In Lavender group in dilatations 4 ;every hour, 3 drops of lavender aroma (Glass labeled 1) Drops on a cotton ball and the patient will be close to their nose and smell it for 10 minutes.

**Category**

Treatment - Drugs

**2****Description**

In valerian group in dilatations 4 cm; every hour, 3 drops of valerian aroma (Glass labeled 2) Drops on a cotton ball and the patient will be close to their nose and smell it for 10 minutes of every hour.

**Category**

Treatment - Drugs

**3****Description**

In Olive oil group in dilatations 4; every hour, 3 drops of Olive oil aroma (Glass labeled 3) Drops on a cotton ball and the patient will be close to their nose and smell it for 10 minutes.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Hazrat Fatemeh Hospital

**Full name of responsible person**

Rana Dosty

**Street address**

Hazrat Fatemeh Hospital,Saheli St, Miandoab, East Azarbayjan.

**City**

Miandoab

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mahin Kamalifard

**Street address**

Nursing and Midwifery, South Shariati Ave.

**City**

Tabriz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tabriz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

empty

**Person responsible for general inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mahin Kamalifard

**Position**

Senior lecturer, Academician

**Other areas of specialty/work****Street address**

Nursing & Midwifery faculty of Tabriz Medical sciences

**City**

Tabriz

**Postal code****Phone**

+98 41 3479 6770

**Fax****Email**

kamalifardm@tbzmed.ac.ir

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Nursing and Midwifery, Tabriz University of Medical Sciences

**Full name of responsible person**

Mahin Kamalifard

**Position**

Master Sciences of Midwifery

**Other areas of specialty/work****Street address**

Nursing and Midwifery, Tabriz University of Medical Sciences

**City**

Tabriz

**Postal code**

**Phone**

+98 914 314 6763

**Fax****Email**

kamalifard@tbzmed.ac.ir

**Web page address****Phone**

+98 914 314 6763

**Fax****Email**

kamalifard@tbzmed.ac.ir

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Nursing and Midwifery, Tabriz University of Medical Sciences

**Full name of responsible person**

Mahin Kamalifard

**Position**

Academic member,MS

**Other areas of specialty/work****Street address**

Nursing and Midwifery, Tabriz University of Medical Sciences, Shariaty st

**City**

tabriz

**Postal code****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*